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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|---------------|----------------------|---------------------|-----------------|
| 10/090,965 | 03/04/2002 | Friedrich Srienc | 110.01480101 | 6415 |
| 26813 75 | 90 04/20/2004 | , | EXAM | IINER! |
| MUETING, RAASCH & GEBHARDT, P.A. | | PAK, YONG D | | |
| P.O. BOX 581415 MINNEAPOLIS, MN 55458 | | ART UNIT | PAPER NUMBER | |
| Will (Wall Obio, Mil Ob 180 | | | 1652 | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|--|--|--|
| | 10/090,965 | SRIENC ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Yong D Pak | 1652 |
| The MAILING DATE of this communication ap Period for Reply | pears on the cover sheet wit | th the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a rep. If NO period for reply is specified above, the maximum statutory period. Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a re oly within the statutory minimum of thirty I will apply and will expire SIX (6) MONT te, cause the application to become ABA | eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on 2/20 | <u>)/2004</u> . | |
| 2a) This action is FINAL . 2b) ⊠ Thi | s action is non-final. | |
| 3) Since this application is in condition for allowa | • | · |
| closed in accordance with the practice under | Ex parte Quayle, 1935 C.D. | 11, 453 O.G. 213. |
| Disposition of Claims | | |
| 4) Claim(s) 1-94 is/are pending in the application 4a) Of the above claim(s) 14-26 and 34-94 is/a 5) Claim(s) is/are allowed. 6) Claim(s) 1-13 and 27-33 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/a | are withdrawn from conside | ration. |
| Application Papers | | |
| 9)☐ The specification is objected to by the Examina | er. | |
| 10)☐ The drawing(s) filed on is/are: a)☐ acc | cepted or b) objected to b | y the Examiner. |
| Applicant may not request that any objection to the | drawing(s) be held in abeyand | ce. See 37 CFR 1.85(a). |
| Replacement drawing sheet(s) including the correct | - · · · · · · · · · · · · · · · · · · · | |
| 11)☐ The oath or declaration is objected to by the E | xaminer. Note the attached | Office Action or form PTO-152. |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documen | | 119(a)-(d) or (f). |
| 2. Certified copies of the priority documen | | oplication No |
| Copies of the certified copies of the price | ority documents have been i | received in this National Stage |
| application from the International Burea | , | |
| * See the attached detailed Office action for a list | of the certified copies not r | eceived. |
| Attachment(e) | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) Interview S | ummary (PTO-413) |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s) |)/Mail Date |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08, Paper No(s)/Mail Date 5/3/03 & 7/23/03. |) 5) ☐ Notice of Int 6) ☐ Other: | formal Patent Application (PTO-152) |

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DETAILED ACTION

The amendment filed on February 20, 2004, adding claim 94, has been entered. Claims 1-94 are pending.

Election/Restrictions

Applicant's election of Group I (claims 1-13, 27-33 and 94) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 94 is directed to a method of producing PHA and ethanol using a transgenic yeast cell comprising a PHA polymerase and/or a β-ketothiolase and an acetoacetyl-CoA reductase. Therefore, claim 94 belongs to Group IV.

Claims 14-26 and 34-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 3, 2003 and July 23, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

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Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-10, 12, 27-28 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Leaf.

Leaf et al. (form PTO-1449 – Dissertation Abstracts International) teach a method of producing polyhydroxyalkanoates (PHA) with a *Saccharomyces cerevisiae* transformed with DNA encoding a *Alcaligene eutrophus* PHA polymerase, a β -ketothiolase and an acetoacetyl-CoA reductase (pages 4287-4288). Therefore, the teachings of Leaf anticipate claims 1, 7-10, 12, 27-28 and 32-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madison et al. in view of Stratagene Catalog.

Madison et al. teach a method of producing PHA in *S. cerevisiae* by introducing DNA encoding an *A. eutrophus* PHA polymerase (page 44). Madison et al. teach that low levels of PHA was due to insufficient activity of the endogenous β-ketothiolase and acetoacetyl-CoA reductase and points to improving PHA yields in *S. cerevisiae* by increasing the activities of these two enzymes.

Further, Madison et al. teach other PHA_{SCL} and PHA_{MCL} that can be used in transgenic yeasts (pages 24-35) and that many different transgenic organisms can be used to produce PHA (page 44), such as a Kluyveromyces, which also belongs to the family of Saccharomycetaceae like *S. cerevisiae*.

The difference between the reference of Madison et al. and the instant invention is that the reference of Madison et al. does not teach a method of producing PHA using a transgenic yeast comprising all three heterologous PHA biosynthesis genes.

However, expression of multiple heterologous genes in yeast is routine in the art. Also, making a single nucleic acid construct composed of more than one gene is also very routine in the art. For example, Stratagene Catalog teach a method of expressing two different genes by using a divergent promoter, wherein the two genes are present in one vector (page 23).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to produce PHA using a transgenic S. cerevisiae comprising of heterologous PHA polymerase, β -ketothiolase and an acetoacetyl CoA- reductase. The motivation of further expressing heterologous β -ketothiolase and an acetoacetyl CoA- reductase is to increase activity of said enzymes to increase the yield of PHA instead of using endogenous β -ketothiolase and an acetoacetyl CoA- reductase. One of ordinary skill in the art would have had a reasonable expectation of success Madison et al. teach that an increase in activity of β -ketothiolase and an acetoacetyl CoA- reductase will increase the yield of PHA.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak Patent Examiner PONNATHAPU ACHUTAMURTHY SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600 Page 5